Exhibit #1

MAY 19 2006

510(K) SUMMARY

This summary of 5l0(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA l990 and 21 CFR §807.92.

The assigned 5l0(k) number is: K060240

1. **Submitter's Identification:**

K-Jump Health Co., Ltd.
No. 56 Wu Kung 5th Rd.
Wu Ku Industrial Park
Taipei Hsien, Taiwan 248
Tel: 886 2 22991378
Fax: 886 2 22991386

Contact: Mr. Danny Wang

Date Summary Prepared: January 27, 2006

2. **Name of the Device:**

K-Jump Digital Thermometer with Battery-Less Patch, Model KD-2100

3. **Common or Usual Name:**

Clinical Electronic Thermometer

4. **Predicate Device Information:**

K003326, Funet Amy Mama Body Thermometer, Funai Radio & Communications Corporation

5. **Device Description:**

The Digital Thermometer with Battery Less Patch, Model KD -2100, consists of a DC battery powered wireless LCD reader and a battery less patch. The LCD reader part consists mainly of a plastic body, four keys (ON/OFF power, memory, read and LED on), two printed circuit boards (CPU and RFID), and an LCD assembly with four backlight LEDs, a buzzer, a battery compartment and four AAA type batteries. The patch part includes a plastic body, a thermister sensor, and a TAG printed circuit board.

K060240

6. **Intended Use:**

The Digital Thermometer with Battery-Less Patch, Model KD-2100, is intended to measure and monitor human body temperature with a wireless digital LCD reader and a sensor coupled patch. The device is reusable and intended for ear and mouth measurement of adults and pediatric patients.

7. **Comparison to Predicate Devices:**

The subject device is substantially equivalent to the predicate device, the Funet Amy Mama Body Thermometer, K#003326. The two devices share the same intended use and indications for use with the exception of small differences in their temperature measurement ranges, transmission frequency, minimum operational temperature and humidity, minimum storage temperature and humidity. These minor technological differences do not raise new issues of safety or effectiveness.

8. **Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:**

The Digital Thermometer with Battery Less Patch, Model KD-2100 complies with EN 60601-1-2 (2001) and ASTM E1112-00 "Electronic Thermometer for Intermittent Determination of Patient Temperature" standard. The conformity of harmonized standards for electronic safety ruled by FCC Part 15 is also included.

9. **Discussion of Clinical Tests Performed:**

Not Applicable

10. **Conclusions:**

The subject device and predicate devices share the same intended use and similar characteristics. Moreover, bench testing contained in this submission demonstrate that any differences in their technological characteristics do not raise any new questions of safety or effectiveness. Thus, the Digital Thermometer with Battery-Less Patch, Model KD-2100, is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 19 2006

K-Jump Health Company Limited
C/O Ms. Susan D. Goldstein-Falk
MDI Consultants, Incorporated
55 Northern Boulevard, Suite 200
Great Neck, New York 11021

Re: K060240
Trade/Device Name: The Digital Thermometer with Battery-Less Patch, KD-2100
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: April 28, 2006
Received: May 1, 2006

Dear Ms. Goldstein-Falk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K060240

Device Name: The Digital Thermometer with Battery-Less Patch, Model KD-2100

Indications for Use:

The Digital Thermometer with Battery-Less Patch, Model KD-2100, is intended to measure and monitor human body temperature with a wireless digital LCD reader and a sensor coupled patch. The device is reusable and intended for ear and mouth measurement of adults and pediatric patients.

Prescription Use _____ (Per 21 CFR 801 Subpart D) OR Over-The Counter Use X (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Sign-Off)
...n of Anesthesiology, General Hospital,
...ion Control, Dental Devices

...Number: K060240